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### REMARKS

Reconsideration of the present application, as amended, is respectfully requested.

Claims 24-45 are pending. Claims 24-25, 27, 33-35, 37-41, 43 and 45 have been amended to more clearly define the invention described therein. The addition of the term, "film," with respect to the "uniform layer" as recited by claim 24, et seq. is supported by the entire specification. In particular, paragraph 2 of the specification [as published] teaches that "[t]he present invention relates to solid gel film compositions..." The examples also confirm that the invention provides a film. For instance, Example 2 provides a process for preparing the inventive composition that concludes with the steps of:

[0052] (i) casting the product of (h) onto a release liner at 15-mil thickness; and,  
[0053] (j) drying the product of (i) in an oven until the film is uniform and not-tacky (about 10 minutes).

Thus, it is submitted that no new matter has been added.

It is urged that it is within the discretion of the Examiner to enter the above-provided amended claims after Final. The Examiner has already analyzed the art of record for the presence of film compositions, as confirmed by the various remarks made in the first and second Office Actions, and as discussed below. Further, it is urged that the provided amendments merely clarify and make express that which was inherently recited by the claims, and place the claims into conditions for allowance. For all of these reasons, entry of the amended claims is respectfully requested.

### **INFORMATION DISCLOSURE STATEMENT**

The Examiner has objected to the photocopied pages of the PTO Form 892 made of record in the parent application that were previously submitted with the Supplemental IDS in the present patent application. That this was the basis for the objection was confirmed during a telephone conference with the Examiner on about November 7.

The Examiner's attention is respectfully directed to 37 C.F.R. § 1.97 (f), second sentence, which states that, "[i]f a *bona fide* attempt is made to comply with § 1.98 but part of the required content is inadvertently omitted, additional time may be given to enable full compliance."

Heretofore, photocopies of 1449 and 892 forms of record in parent patent applications have generally been accepted by Examiners as making parent references of record in a child patent

application. Since the Examiner has objected to this practice as to PTO Form 892 in the instant patent application, Applicants urge that the previous submission be treated as a *bona fide* attempt to comply with § 1.98. Thus, Applicants enclose herewith a replacement PTO Form identified as "Information Disclosure Statement" according to the current form practice (previously known as a PTO Form 1449) for the convenience of the Examiner in checking off the references made of record in parent patent Ser. No. 09/340,338 on PTO Form 892. This should be treated as correction of the previous *bona fide* submission and not as a new submission.

The previous form 892 repeated the reference alphabetic designations for each page of the 892 listing, thus, it is noted that the enclosed replacement listing simply lists the references in numerical order, starting with the number "1". Copies of all references are in the file of Ser. No. 09/340,338.

For all of these reasons, it is urged that this ground of objection is now obviated.

#### **THE CLAIMED INVENTION IS NOVEL UNDER 35 U.S.C. 102(e)**

At item 2 of the Office Action, the Examiner has maintained the rejection of claims 24-34, 35-40 and 43-45 under 35 U.S.C. 102(e) as allegedly anticipated by Biedermann et al. (U.S. 5,980,921) (hereinafter "Biedermann"). The Examiner has reiterated the position that Biedermann describes a topical composition "formulated as a cleansing composition in the form of bath gels, liquid, shampoos, hair tonic, pastes and mousses..." that also can comprise a "film forming polymer that is not tacky..." At page 4 of the Office Action, under the heading, "Response to Arguments," the Examiner takes the position that,

The physical form of the Biedermann cleansing formulation is "toilet bars, liquids, shampoos, bath gels, hair conditioners, hair tonics, pastes, or mousses. *Toilet bars* are most preferred since this is the form of cleansing agent most commonly used to wash the skin," (column 6, lines 41-44).

At the top of page 5 of the Office Action, the Examiner further states that:

Regarding applicant's argument that Biedermann's formulation is not a dry uniform layer, it is noted that one of the physical forms of Biedermann's formulation is a toilet bar (column 6, line 41) and a toilet bar which is used as a cleansing agent is .dry and of uniform layer such that applicant's claim to a broad water-dissolvable, non-tacky and dry uniform layer reads on Biedermann's toilet bar.

Applicants respectfully disagree. In order to anticipate a claimed invention, a reference must describe each and every element of the invention as claimed. Claim 24 now recites:

A delivery device comprising a water-dissolvable, non-tacky, *dry uniform film layer*, wherein the uniform film layer comprises a water-dissolvable filmogenic polymer and an effective dose of an active substance, and wherein the *uniform film layer is dissolvable upon application* onto a wetted skin tissue or mucosal epithelial tissue of a subject, and wherein *the delivery device is suitable for application to skin or mucosal epithelial tissue of a subject.* (Italics added for emphasis).

The claimed invention provides a "delivery device" that includes a "dry uniform film layer," that is "suitable for application to ....a subject." The dry uniform film layer is dissolvable upon application onto a wetted skin tissue..." It is submitted that claim 24 excludes a liquid, cream or toilet bar as described by Biedermann. A film is defined, *inter alia*, by the Webster's Ninth New Collegiate Dictionary<sup>1</sup> as, "a thin covering or coating" or "an exceedingly thin layer." That this is the meaning of the term in the present application is made clear by the examples, that describe casting exemplary films in a 15-mil thickness.<sup>2</sup>

It is respectfully submitted that Biedermann fails to describe or suggest any such delivery device. Instead, Biedermann describes an aqueous composition for application to skin, or toilet bars that, by their very nature, could not fall within the definition of a "uniform film layer" as required by claim 24, et seq. The phrase, "wherein the uniform film layer is dissolvable..." is respectfully urged to make it clear that the claimed device is dry before contact with skin. The Biedermann composition is clearly not a "dry uniform film layer" before contact with skin. While the Biedermann composition may hypothetically form a dry film after contact with skin, it is urged that such a film formed on the skin, after application, is not a dry uniform film layer that is suitable for application to the skin, as required by claim 24, et seq.

In addition, it is submitted that Biedermann fails to describe or suggest the methods of claims 43-45, since those claims require that the applied device with a uniform film layer be dry before application to the skin or mucosal surface the recited process.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

<sup>1</sup> Webster's Ninth New Collegiate Dictionary, page 463, Copyright 1988. Photocopy of pertinent pages enclosed. Box outlines entry for "film" for the examiner's convenience.

<sup>2</sup> E.g., Example 2; 15 mils is 15/1000th of an inch.

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**THE CLAIMED INVENTION IS NONOBVIOUS UNDER 35 U.S.C. 103(a)**

At item 5 of the Office Action, the rejection of claims 35 and 42 under 35 U.S.C. 103(a) as allegedly obvious over Biedermann, taken alone, is maintained. The Examiner apparently takes the position that the toilet bar described by Biedermann falls within the scope of the claims 35 and 42, without the necessity of pointing to any additional reference to remedy the clear deficiencies of Biedermann as a reference under 35 U.S.C. 102, as discussed above.

Applicants respectfully disagree. In order to sustain a *prima facie* obviousness rejection under 35 U.S.C. 103(a), the Patent Office has the burden of coming forward with a combination of references, or with a reference and other information from the state of the art, from prior to the filing date (priority date) of the subject patent application, showing all of the elements of the invention as claimed, and a suggestion or reason why the artisan would have made the alleged combination, that is found in the references or state of the art.

It is respectfully submitted that the instant rejection simply fails to meet the requirements of the law, particularly when taken in view of the presently pending claims. The shortcomings of Biedermann as an anticipatory reference are discussed above.

Further, the Examiner has not made the required showing that any element(s) missing from Biedermann as a reference, for example, the requirement for a "uniform film layer" in the device before application to skin or mucosal epithelial tissue, are provided by another reference or the state of the art, and why such other reference would have been considered by the ordinary artisan. In an abundance of caution, it is also respectfully requested that, if the Examiner is basing her rejection under 35 U.S.C. 103(a) on personal knowledge, she make such personal knowledge of record in the form of a Declaration Under 37 C.F.R. 1.132.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**CONCLUSION**

This response is being timely filed. No fee is believed to be due. If, on the other hand, it is determined that any fees are due or any overpayment has been made, the Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for

extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

In view of the actions taken and arguments presented, it is respectfully submitted that each of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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